REMARKS

This amendment is submitted under 37 CFR 1.116 after final rejection because applicants believe that all claims now presented are in condition for allowance. In any event entry of this amendment will place the application in better form for appeal. No new mater has been added and no new issues have been raised. Finally the arguments presented herein are in direct response to points raised by the examiner in the last office action, and Applicants could not have filed their response at an earlier date.

Applicants have amended claim 40 in order to make the correction requested by the Examiner on page 9 of the office action. Applicants have also amended claim 48 in response to the Examiner's rejection of that claim under 35 USC 112, second paragraph, as indefinite. Applicants have amended claim 48 to make it clear that the vaccinia virus host range genes or homologs thereof are in the vaccinia viral genome and not in the avipoxviral genome. Antecedent basis for the amendments to claim 48 may be found in the specification on page 5, lines 13 to 23, and in Example 1 on pages 21 through 29 of the specification. Applicants believe that all claims now presented comply with all requirements of 35 USC 112, second paragraph.

The Examiner has rejected claims 48, 50 and 51 under 35 USC 112, first paragraph, on the grounds that the claims are not supported by a specification that complies with the enablement requirement found in this section of the statute. The Examiner argues that the preparation of the isolated avian cell requires the integration of a vaccinia virus host range gene into an avian host cell genome, and that it is not apparent from the specification that such a cell may be obtainable by a repeatable method without the need to conduct undue experimentation.

Applicants do not believe that the Examiner's request for a microbiological deposit is justified. Applicants are not preparing an avian host cell in which is integrated a vaccinia virus host range gene. Applicants are preparing avian cells, infected with a recombinant avipoxvirus containing a vaccinia virus host range gene having an increased viral titer over that of a corresponding avipoxvirus without said vaccinia virus host range gene added to said avipox viral genome. Example 1 of the present application is easily reproducible by one "skilled in the art" and so one "skilled in the art" could replicate Example 1 of the present application to obtain the recombinant avipoxvirus without the need to conduct undue experimentation. In the event that claim 48 as last presented did not clearly indicate same, Applicants have amended that claim so that the nature of the recombinant avipoxvirus is clearly set forth. Thus claims 48, 50 and 51 fully

comply with the enablement requirement of 35 USC 112, first paragraph.

The Examiner maintains that claims 32, 35, 36 through 40, 45, 50, and 52 through 55 are anticipated by US Patent 6,004,777 to TARTAGLIA et al, and has maintained a rejection of those claims under 35 USC 102. The Examiner agrees in the last paragraph of page 3 of the office action that TARTAGLIA et al does not teach an increased titer of an avipoxvirus as a result of a vaccinia virus host range gene being inserted into the avipoxviral genome. Nonetheless, the Examiner appears to argue that inherently the ALVAC recombinants, disclosed in col. 27, lines 56 to 64 of TARTAGLIA et al, containing the E3L/K3L cassette (vCP1431A) when grown in cells such as CEFs, anticipate or at least render obvious the invention in present claim 32 . The ALVAC virus is a canary poxvirus. CEFs are disclosed in col. 28, line 9 of TARTAGLIA et al. The Examiner has specifically taken note in the last sentence of the central paragraph of page 2 of the office action of the language "grown in avian cells" in line 1 of claim 32, but refuses to give this expression any consideration apparently arguing that this expression has relevance only in claims directed to a process for preparing the recombinant avipoxvirus, and not claims directed to the recombinant avipoxvirus per se. See page 4, lines 7 and 8 of the office action.

The Examiner has not been entirely clear why he believes that TARTAGLIA et al anticipates claim 32 when the specified Vaccinia Virus host range genes include only C18L, C17L, C7L, K1L, B4R, B23R, and B24R with no mention of the E3L and K3L vaccinia virus genes. It appears from the last paragraph of page 3 of the office action that the Examiner regards the vaccinia virus E3L and K3L genes to be homologous with the host range genes specified in claim 32, and claim 32, line 4, includes "or a homolog thereof" after the specified vaccinia virus host range genes. Perhaps the Examiner bases his conclusion that the E3L and K3L vaccinia virus genes are homologous to the host range genes specified in claim 32 relying on page 5, lines 28 to 29 where it states that the "homologue of the host range gene" has the biological activity of a host range gene.

Applicants strongly believe that TARTAGLIA et al neither anticipates under 35 USC 102 nor renders obvious under 35 USC 103 any claim now presented. TARTAGLIA et al discloses ALVAC recombinants containing the E3L and the K3L host range genes. Contrary thereto, claim 32 and the other claims now presented relate to an avipoxvirus comprising a vaccinia virus host range gene selected from the group consisting of C18L, C17L, C7L, K1L, B4R, B23R, and B24R. Neither the E3L or the K3L host range genes are included in any claim now presented.

According to the presently claimed invention, including one of the specified vaccinia virus host range genes in an avipoxvirus surprisingly results in an increased viral titer for the avipoxvirus. Thus, while TARTAGLIA et al relates to vectors having enhanced expression, specifically an improved expression of heterologous antigens, the presently claimed invention relates to achieving an increased titer of an avipoxvirus. TARTAGLIA et al does not disclose or suggest that an avipoxvirus containing a vaccinia host range gene would have an increased titer in permissive cells.

Furthermore, neither of the E3L or the K3l host range genes disclosed in TARTAGLIA et al is homologous to any of the host range genes within the scope of present claim 32 or any of the other claims in this application. Applicants are enclosing two alignment sets of polynucleotides, one set compares the E3L host range gene against each of the host range genes listed in present claim 32 and the second set compares the K3Lhost range gene against each of the host range genes listed in present claim 32. The alignments clearly show that homology is lacking between either the E3L or the K3L host range genes of TARTAGLIA et al and the hose range genes included in the presently claimed invention. Since the host range genes ain TARTAGLIA et al are not homologous with the host range genes in the presently claimed invention, not only is TARTAGLIA et al not anticipatory of any claim now presented, but furthermore TARTAGLIA et al provides no basis to reject any claim

now presented as obvious under 35 USC 103 since there is nothing disclosed in TARTAGLIA et al that would suggest that vaccinia virus host range genes of the structures defined in present claim 32 when combined with an avipoxvirus through homologous recombination would lead to recombinant avipoxviruses with a surprisingly high viral titer when grown in avian cells.

The mention in TARTAGLIA et al of CEF cells in col. 28 refers to a prior art reference, and does not relate to the ALVAC virus containing the E3L/K3L cassette. There is no mention of CEF cells or any other avian cells in TARTAGLIA et al that contain the ALVAC virus or any other avipoxvirus containing the E3L/K3L cassette. Thus Applicants have retained the expression "grown in avian cells" in claim 32, and reiterate that this expression should be taken into consideration by the Examiner in determining whether the claims are anticipated or obvious in view of TARTAGLIA et al. Furthermore now that Applicants have provided comparative sequence data showing that the structure of the E3L and K3L host range genes disclosed in TARTAGLIA et al are not homologous with the host range genes as included in the present claims, it is not even necessary that Applicants include the expression "grown in avian cells" to patentably distinguish their presently claimed invention over TARTAGLIA et al.

The Examiner has rejected claims 45, 48 through 50, and 52 through 56 under 35 USC 102 as anticipated by CARDONA et al.

The Examiner argues that the reference discloses chicken embryo fibroblasts (CEFs) and their use in tissue culture procedures. The Examiner concludes that even though CARDONA et al does not teach the Applicants' claimed recombinant avipoxvirus replicated in the CEF cells, that is irrelevant since the claimed invention is drawn to an isolated avian cell, not the virus. Furthermore the presence of the recombinant avipoxvirus in the isolated avian cell does not alter the cell in such a way as to make it patentably distinct from the same isolated avian cell free from the avipoxviruses.

Applicants do not agree with the Examiner's argument that claims 45, 48 through 50, and 52 through 56 are anticipated by newly cited CARDONA et al. By "isolated avian cell" Applicants do not mean an avian cell free of the recombinant avipoxvirus as clearly can be determined by a plain reading of the claims. The term "isolated: merely means that the cell has been separated from the avian host. The Examiner argues that there is no difference between avian cells such as CEFs per se and avian cells such as CEFs containing the recombinant avipoxvirus containing a specified Vaccinia Virus host range gene. Applicants disagree. Applicants' isolated avian cells containing the recombinant avipoxvirus according to the invention do have advantages over isolated avian cells per se without the recombinant avipoxvirus .

The avian cells containing the recombinant avipoxvirus have other properties and advantages over the CEFs per se. The

advantage of a high viral titer avian poxvirus lies in the facilitation of production of avipoxviruses on a large scale in the field of recombinant virology/vaccine production. Avipoxviruses, such as canary poxvirus, are known to grow only to relatively low titers, and to grow more slowly than the other poxviruses. Therefore introducing vaccinia virus host range genes into the avipoxviral genome have proved to be a good tool to increase the production of an avipoxvirus such as canary poxvirus. Since CARDONA et al neither discloses introducing vaccinia virus host range genes into the avipoxviral genome, nor suggests any advantage thereto, the reference provides no basis to reject any claim now presented as anticipated under 35 USC 102 or as obvious under 35 USC 103.

The Examiner has rejected claims 33, 34 and 60 under 35 USC 103 as obvious citing the combination of TARTAGLIA et al, ANTOINE et al and FIELDS et al. The Examiner admits that TARTAGLIA et al does not teach the insertion of the host range genes C17L, C18L, C7L, K1L, B4R, B23R, or B24R, into an avipoxvirus, for any purpose, let alone for the purpose of increasing the viral titer of the avipoxvirus. However, the Examiner believes that because TARTAGLIA et al teach that the E3L or K3L host range gene may be added to canary pox virus or fowlpox virus to increase the expression of a heterologous gene also added to the avipoxviral genome, that the presently claimed invention would be obvious from ANTOINE et al and FIELDS et al because the secondary references

disclose the open reading frame for vaccinia virus comprising all of the Applicants' specified host range genes, is the same.

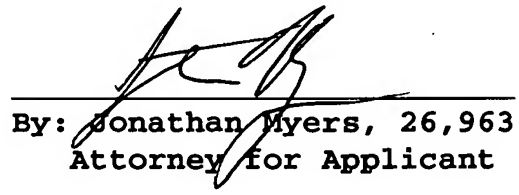
Applicants strongly disagree. Te Examiner admits that TARTAGLIA et al does not disclose the host range genes C17L, C18L, C7L, K1L, B4R, B23R, or B24R from vaccinia virus for any purpose, but he does not acknowledge that TARTAGLIA et al fails to disclose or suggest that inclusion of one of the above mentioned host range genes into an avipoxvirus surprisingly yields a high viral titer of said recombinant avipoxvirus. Such a high viral titer, is, as outlined above, highly advantageous in the field of recombinant virology/vaccine production. Neither of ANTOINE et al nor FIELDS et al discloses or suggests obtaining a high viral titer of an avipoxvirus by including a vaccinia virus host range gene into an avipoxvirus. Furthermore the fact that all of the Applicants' host range genes may be from the same open reading frame of vaccinia virus is irrelevant, since Applicants have shown with directly comparative sequence listings that the E3L and K3L host range genes disclosed in TARTAGLIA et al are structurally far removed from the host range genes employed according to the present invention. Since the Applicants' specified host range genes are structurally far removed from the E3L and K3L host range genes of TARTAGLIA et al, no common properties presumption exists between those E3L and K3L host range genes disclosed in TARTAGLIA et al and those specific host range genes included in the present invention, regarding either the ability to facilitate expression of a

heterologous sequence in an avipoxviral genome as disclosed in TARTAGLIA et al or the ability to increase the viral titer of an avipoxvirus grown in avian cells as disclosed in the present invention. Since none of the cited references, either alone or in combination suggests all of the requirements of the present set of claims, Applicants believe that this combination of references provides no basis to reject any claim now presented as obvious under 35 USC 103.

Applicants believe that claims 32 through 40, 45, 48 through 56, and 50 are in condition for allowance and a response to that effect is earnestly solicited. Furthermore in view of Applicants' arguments for the allowance of these claims, the Examiner is asked to rejoin claims 41 through 44, 46, 47, and 57 through 59 and allow those claims as well. It is noted that the claims withdrawn from further consideration include the same vaccinia virus host range genes as the claimed under examination and so are commensurate in scope in this respect.

Applicants enclose a petition to obtain a one month extension of the term for response and a completed Form PTO 2038 to enable charging the cost of obtaining the extension to the credit card of the undersigned attorneys.

Respectfully submitted,
K.F. Ross P.C.



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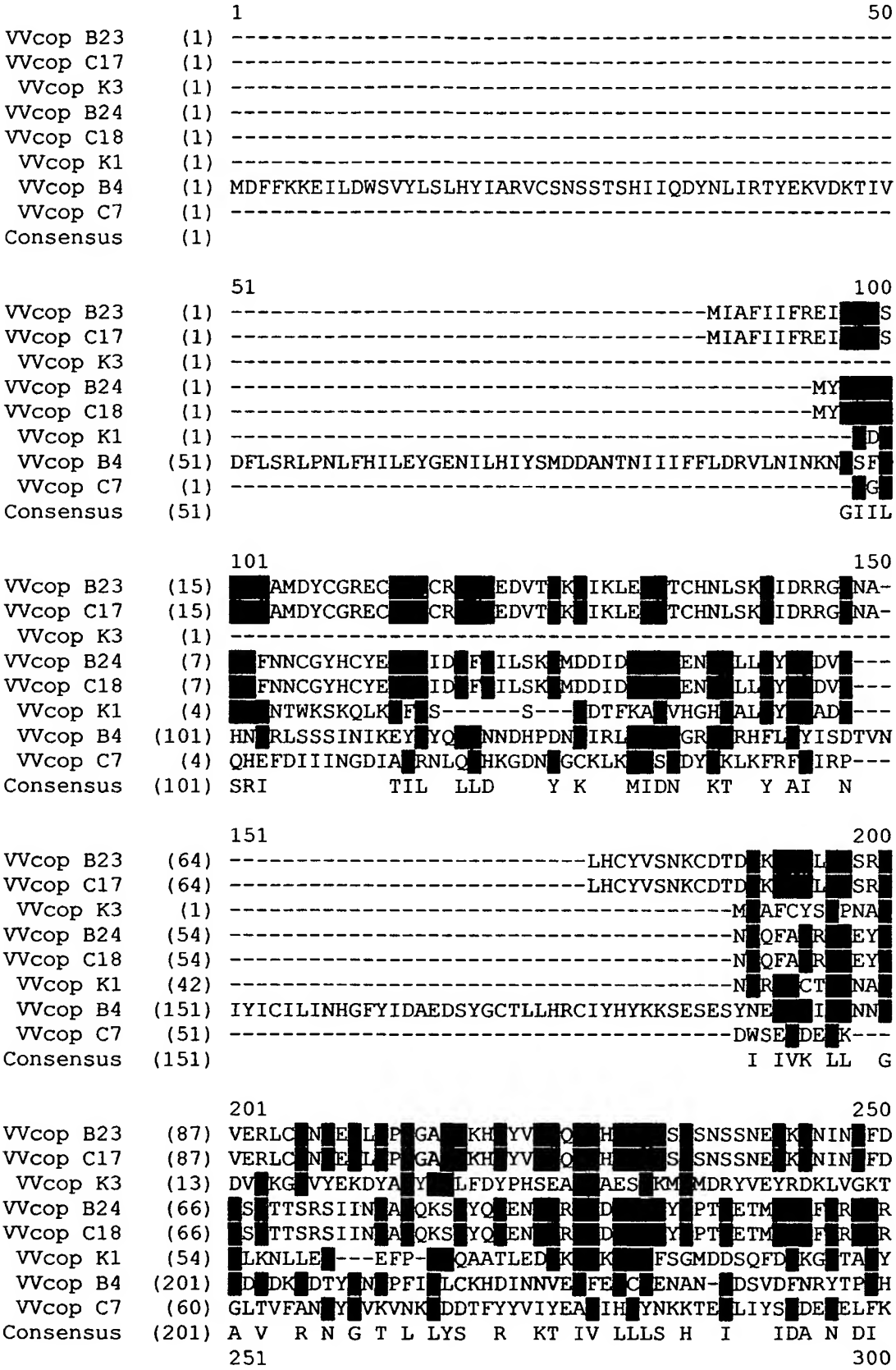
Enclosures:
Request for extension (one month)
PTO 2038 Form
2 Comparative Sequence Listings

ge/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51 100
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VVcop B4 (201) D DK DTY N PFI LCKHDINNVE FE C ENAN- DSVDFNRYTP H
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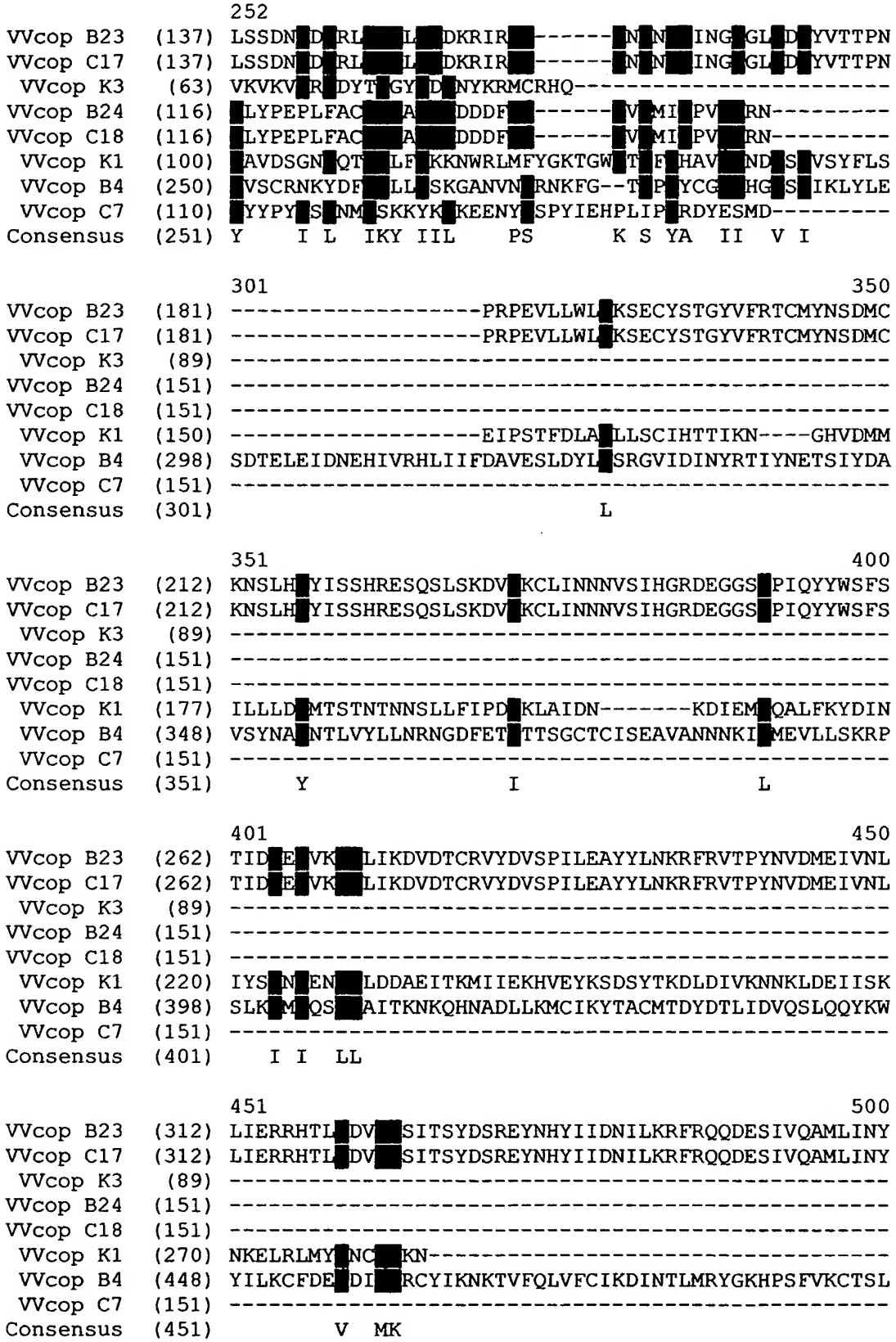
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301 350
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VVcop K3 (89) ----------
VVcop B24 (151) ----------
VVcop C18 (151) ----------
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VVcop C7 (151) ----------
Consensus (301) L
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VVcop B24 (151) ----------
VVcop C18 (151) ----------
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401 450
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VVcop C18 (151) ----------
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VVcop C7 (151) ----------
Consensus (451) V MK

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VVcop B24   (151) -------------------------------------------------
VVcop C18   (151) -------------------------------------------------
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 VVcop C7   (151) -------------------------------------------------
Consensus   (501)

                551      562
VVcop B23   (387) ------------
VVcop C17   (387) ------------
 VVcop K3    (89) ------------
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VVcop C18   (151) ------------
 VVcop K1   (285) ------------
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 VVcop C7   (151) ------------
Consensus   (551)
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Consensus positions: 15.8%
Identity positions: 0.0%

Alignment Coloring Scheme

Residues in an alignment are colored according to the following scheme:

black on window default color	**non-similar residues**
blue on cyan	consensus residue derived from a **block of similar residues at a given position**
black on green	consensus residue derived from the **occurrence of greater than 50% of a single residue at a given position**
red on yellow	consensus residue derived from a **completely conserved residue at a given position**
green on window default color	residue weakly similar to consensus residue at given position

Software used: Vector NTI/AlignX from Invitrogen

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     VVcop E3     (1) --------------------------------------------------
    Consensus     (1)

                         51                                                 100
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    Consensus    (51)

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     VVcop C7     (1) --------------------------------------------------
     VVcop E3     (1) --------------------------------------------------
    Consensus   (101)

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     VVcop C7    (1) --------------------------------------------------
     VVcop E3    (1) -------------------------MSKIYIDERSDAEIVCAAIKNIGI
    Consensus  (151)                              I       S     AI  L

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                        451                                                 500
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    Consensus   (451)

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     VVcop C7   (151) --------------------------------------------------
     VVcop E3   (191) --------------------------------------------------
    Consensus   (501)

                        551     561
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    Consensus   (551)
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Consensus positions: 10.2%
Identity positions: 0.0%

Alignment Coloring Scheme

Residues in an alignment are colored according to the following scheme:

black on window default color	**non-similar residues**
blue on cyan	consensus residue derived from a **block of similar residues at a given position**
black on green	consensus residue derived from the **occurrence of greater than 50% of a single residue at a given position**
red on yellow	consensus residue derived from a **completely conserved residue at a given position**
green on window default color	residue weakly similar to consensus residue at given position

Software used: Vector NTI/AlignX from Invitrogen